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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,125	08/05/2003	Kazunobu Okazaki	Q76820	5755

23373 7590 08/19/2009

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EXAMINER	
QAZI, SABIHA NAIM	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
08/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/634,125	OKAZAKI ET AL.	
	Examiner	Art Unit	
	Sabiha Qazi	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,11,13-15 and 17-20* is/are pending in the application.

4a) Of the above claim(s) *11,13,15,18 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10, 14, 17 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *11,13,15,18 and 19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Final Office Action

Claims 10, 11, 13-15 and 17-20 are pending. No claim is allowed at this time.

Amendments are entered.

Summary of this Office Action dated August 14, 2009

1. Information Disclosure Statement
2. Copending Applications
3. Specification
4. 35 USC § 103 Rejection
5. Response to Remarks
6. Conclusion
7. Communication

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Copending Applications

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See Dayco Products Inc. v. Total Containment Inc., 66 USPQ2d 1801 (CA FC 2003).

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10, 14, 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over EMOTO, MITSUO (US Patent 6,458, 395) and DAVENPORT et al. (J. Dairy Sci. 83:2819; 892 references). The references teach a composition and process of making a nutritional supplement using whey protein, hydrogenated soybean, organic acid vitamin D and various other ingredients, which embraces presently claimed invention.

EMOTO teaches that the proteins can be used singly or in combination. See lines 42-54 in column 4gelled foods and processes for producing such foods by using gelling agents. when specific amounts of lipid, saccharide, organic acid, organic acid salt, emulsifying agent and gelling agent are added to a protein so as to obtain an emulsion having an acidic pH equal or close to the isoelectric point of the protein, a composite of an isoelectric gel of the protein and a gel formed with the gelling agent is obtained, which is soft and homogeneous and capable of being swallowed without chewing.

The reference teaches a gel of an emulsified mixture comprising 10 to 50 wt. % of the combined amount of the ingredients listed below (on a dry weight basis) and 50 to 90 wt. % of water, and which has a **pH of 3.3 to 4**, and which is a composite of an isoelectric gel of the protein and a heat-soluble gel formed with the gelling agent and good storage stability because of its pH of 3.3 to 4, preferably 3.5 to 4. Moreover, in spite of the acidic pH, the food product of the invention is free from grains of **coagulated protein,** and has smoothness and homogeneity that impart good eating qualities and textural properties to the food product. The ingredients and proportions of the gelatinous food product of the invention are described in the references (see the abstract and lines 4-10 in column 3).
The gelatinous food product of the invention has good eating qualities and can be

safely eaten by patients with dysphagia associated with various diseases or following surgical operations, the food product being capable of supplying well balanced nutrition. Further, the food product of the invention is suitable for not only the patients but also healthy people, for example, athletes who need to obtain nutrition quickly during training or competition.

It further teaches that the protein, one of the essential ingredients of the gelatinous food product of the invention, is selected from ones conventionally used in the field of food products. It is necessary that the protein form an isoelectric gel at the pH of the food product of the invention, i.e., pH 3.3 to 4. Examples of such proteins include gelatin, casein, whey proteins (e.g., lactalbumin), soybean protein and wheat protein; salts of these proteins; decomposition products (acid decomposition products and enzyme decomposition products) of these proteins; extracts of these proteins; concentrates of these proteins; and whole milk powders and skimmed milk powders. The proteins may be used singly or in combination. The protein is present in the food product of the invention in a proportion of about 2 to 60%, preferably about 10 to 45%, more preferably about 15 to 30% on a dry weight basis. Proportions less than 2% or more than 30% are not preferable, since the resulting food product does not satisfy the requirements for nutritionally balanced food products.

The reference also teaches organic acids and vitamins including vitamin D as ingredients (lines 1-20 and 55-68 in column 5, lines 1-12 in column 6). See examples and claims.

DAVENPORT teaches use of colostrum supplement with whey protein concentrate or casein. It further teaches that plasma volume expands with colostrum intake (see the entire document especially abstract, first para in column 2 on page 2815 and table 1 on page 2816). Colostrum is breast milk so it contains natural calcium, carbohydrates, fat and water. The reference teaches the combination of whey protein and casein.

It would have been obvious to one skilled in the art at the time of invention to prepare a nutritional supplement containing a protein which does not coagulate at 3.3 to PH 4 (whey protein, as in the disclosure of the present invention and colostrum) and vitamin D and other ingredients in the form of a gel because prior art teaches the nutritional supplement and process of making them in the form of a gel. One skilled in the would know that calcium in natural from, acids, carbohydrates, fat and water all are present in milk which expands plasma volume. One skilled in the art would also know to add emulsifying agent and agar because prior art also teaches the use of these components. Motivation has been provided by the reference. Since no new concept and/or improvement were noted therefore presently claimed invention has been considered obvious over the prior art of record.

The proportions and percentage are taught by the references. Even if these were not in the ranges court has decided that normally, change in temperature, concentration, or both, is not a patentable modification; however, such changes may impart patentability to a process if the ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from results of prior art; such ranges are termed "critical" ranges, and applicant has burden of proving such criticality; even though applicant's modification results in great improvement and utility over prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art; more particularly, where the general conditions of the claim are disclosed in the prior art, it is not inventive to discover optimum or workable ranges by routine experimentation. In re Aller et al. 105 USPQ 233. The formulation as gel would have been obvious to one who is familiar with the art.

It is well established that merely selecting proportions and ranges is not patentable absent a showing of criticality. In re Becket, 33 U.S.P.Q. 33 (C.C.P.A. 1937). In re Russell, 439 F.2d 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971).

Since no criticality and/or unexpected results are seen presently claimed invention is considered obvious over the prior art of record.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Response to Remarks

Applicants' arguments have been fully considered but are not found persuasive. Rejections not reiterated from previous office actions are hereby withdrawn. The following rejections are reiterated and constitute the complete set presently being applied to the instant application.

Applicant argues that amended claims are not obvious over EMOTO because it fails to teach the protein which does not coagulate at pH 3.3 to 4 and also fails to teach protein hydrolysate of average molecular weight 5000-10, 000. Examiner disagrees because EMOTO teaches (1) whey protein which has been claimed and disclosed in specification.(therefore expected to have the molecular wt the same as claimed (2) it further suggests that a gelling agent may be employed for the formation of the beverage gel. As a result it would be obvious to one skilled in the art, that if a protein that does not coagulate at low pH is employed, a

gelling agent can be used to impose the gelling properties of the gel beverage. On the other hand, employing protein hydrolysates which do not coagulate at low pH is obvious to one skilled in the art.

It has been decided by the courts that "when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S,Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is… a person of ordinary creativity, not an automaton." Id. at 1742.

See In re Levin, 84 USPQ 232, In re Benjamin D. White, 17 C.C.P.A. (PAtents) 1144, 156 F, 2d 189, 70 USPQ 221.

Applicant's election of group I, claims 10, 14, and 17 with traverse. Applicant argues that since both groups I and II are drawn to method of increasing the plasma volume therefore, no restriction should have been made. Restriction was made because both the methods as claimed are considered different. Claims of group I are

drawn to a method containing a gel composition which can be **used topically** wherein invention of group II is drawn to a gel composition **containing food.** One reference may not be applicable to both the methods. Examiner will withdraw the restriction requirement if Applicants on record agree that when any reference used to reject one method can be used for the other and therefore there is no difference.

New claim 20 previous added is drawn to gel composition contained in food and should be included in the group II. Again, Examiner will join the withdrawn groups if Applicants establish that there is no distinguish on between the inventions and all the invention is drawn to same subject matter.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/
Primary Examiner, Art Unit 1612